PANEL RECOMMENDATION OPTIONS
for
PREMARKET APPROVAL APPLICATIONS

The Medical Device Amendments to the Federal Food, Drug and Cosmetic Act (ACT), as amended by the Safe Medical Devices Act of 1990, allows the Food and Drug Administration to obtain a recommendation from an expert advisory panel on designated medical device premarket approval applications (PMAs) that are filed with the Agency.

The PMA must stand on its own merits and your recommendation must be supported by safety and effectiveness data in the application or by applicable publicly available information. Safety is defined in the Act as reasonable assurance, based on valid scientific evidence that the probable benefits to health (under conditions on intended use) outweigh any probable risks. Effectiveness is defined as reasonable assurance that, in a significant portion of the population, the use of the device for its intended uses and conditions of use (when labeled) will provide clinically significant results.

Your recommendation options for the PMA vote are as follows:

1. **APPROVAL** – If there are no conditions attached.

2. **APPROVABLE with conditions** – The panel may recommend that the PMA be found approvable subject to specified conditions, such as physician or patient education, labeling changes, or a further analysis of existing data. Prior to voting, all of the conditions should be discussed by the Panel.

3. **NOT APPROVABLE** – The panel may recommend that the PMA is not approvable if:

   ✍✍The data DO NOT provide a reasonable assurance that the device is safe,

   or

   ✍✍If a reasonable assurance HAS NOT been given that the device is effective, under the conditions of use prescribed, recommended, or suggested in the proposed labeling.

Following the voting, the Chair will ask each panel member to present a brief statement outlining the reasons for his or her vote.

Effective: June 14, 1999